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SEP - 2 1999

Ted K. Ringsred
3M/Office of Intellectual Property Counsel
P.O. Box 33427
St. Paul, MN 55133-3427

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,238,944

#19

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,238,944, which claims the human drug product ALDARA™ (imiquimod) and the method of use of ALDARA™, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 187 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Applicant is required to elect a single patent to be extended under 35 U.S.C. § 156 within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to these time periods. In the absence of such request for reconsideration and if the above-identfied patent is elected, the Commissioner will issue a certificate of extension, under seal, for a period of 187 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of October 20, 1998 (63 Fed. Reg. 56035). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (3,254 - 2,184) + 217
= 734 days

Since the regulatory review period began September 1, 1987, before the patent issued (August 24, 1993), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From September 1, 1987 to August 24, 1993 is 2,184 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 734 days, would extend the patent from August 24, 2010 (35 U.S.C. § 154) to August 27, 2012, which is beyond the 14-year limit (the approval date is February 27, 1997, thus the 14 year limit is

February 27, 2011). The period of extension is thus limited to February 27, 2011, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, August 24, 2010, to and including February 27, 2011, or 187 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Applicant has also filed an application for patent term extension of U.S. Patent No. 4,689,338 based upon the regulatory review of ALDARA™. No more than one patent may be extended for a regulatory review period of a single product. 35 U.S.C. § 156(c)(4). When applications are filed for extension of the terms of different eligible patents based upon the same regulatory review period for a product, the certificate of extension is issued to the eligible patent having the earliest date of issuance unless applicant elects a different eligible patent. Therefore, only one of above-identified patent and U.S. Patent No. 4,689,338 can be extended based upon the regulatory review period of ALDARA™. Accordingly, applicant is required to elect a single patent upon which the extension will be based. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent will be granted and the application for U.S. Patent No. 5,238,944 will be dismissed.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	5,238,944
Granted:	August 24, 1993
Original Expiration Date:	August 24, 2010
Applicant:	Steven M. Wick, et al.
Owner of Record:	Riker Laboratories
Title:	Topical Formulations and Transdermal Delivery Systems Containing 1-Isobutyl-1H-Imadazo[4,5-C]Quinolin-4-Amine
Classification:	514/293
Product Trade Name:	ALDARA™

Term Extended: 187 days

Expiration Date of Extension: February 27, 2011

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
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RE: ALDARA™
FDA Docket No.: 97E-0269